PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P20066PC00	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2005/000135	International filing date *(day/month/year)* 2 February 2005	Priority date *(day/month/year)* 4 February 2004

International Patent Classification (IPC) or national classification and IPC

Int. Cl.

A61N 1/05 (2006.01) *A61F 2/48* (2006.01)

Applicant

VENTRACOR LIMITED et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:

a. [X] *(sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:

- [X] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
- [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

This report contains indications relating to the following items:

[X]	Box No. I	Basis of the report
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[ ]	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18 August 2005	20 January 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **XAVIER GISZ** Telephone No. (02) 6283 2064

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2005/000135

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

[X] The international application in the language in which it was filed

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (under Rules 12.3(a) and 23.1 (b))

[ ] publication of the international application (under Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

[ ] the international application as originally filed/furnished

[X] the description:

pages **1, 2, 4-12** as originally filed/furnished
pages* **3** received by this Authority on **18 August 2005** with the letter of 18 August 2005
pages* received by this Authority on with the letter of

[X] the claims:

pages **14** as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **13** received by this Authority on **18 August 2005** with the letter of 18 August 2005
pages* received by this Authority on with the letter of

[X] the drawings:

pages **1/4 – 4/4** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2005/000135

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-7	YES
	Claims		NO
Inventive step (IS)	Claims	1-7	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Claims 1-7 meet the criteria set forth in PCT Articles 33(2) and 33(3) for novelty and inventive step. The prior art published before the priority date does not disclose or obviously suggest a percutaneous lead assembly for supplying signals to an implanted medical device, said lead assembly comprising a flexible elongate member having a first thick (or shielded portion) adapted to remain external to the body of a patient, and a second thin (or unshielded) portion to extend through a hole in the skin of patient as presently defined.

a hole in a skin layer of the body of the patient, and wherein said second portion having a second diameter which is substantially smaller than said first diameter.

Preferably, said first portion may include a shielding layer. Additionally, at least a segment of said second portion may be covered with a textured surface.

Preferably, said first portion and said second portion may be joined by connectors and said percutaneous lead assembly may include a lead restraint.

Preferably, said lead restraint is implanted within a body of a patient and extends through a hole in the patient's skin and characterised in that an excess length of lead is releasably secured near to the hole by releasable securing means affixed to the patient's skin.

In another broad form of the present invention, a percutaneous lead assembly for supplying electrical signal to a medical device implanted within a body of a patient, wherein said lead assembly has a flexible elongate member including a first unshielded portion that extends through a hole in a skin layer of the body of the patient; and a second shielded portion which is joined to said first unshielded portion at a site external to the body of the patient.

Brief description of the drawings

Embodiments of the present invention will now be described with reference to the accompanying drawings wherein:

Figure 1 shows a schematic view of a first preferred embodiment of the present invention, in situ;

Figure 2 shows a cut away side view of a portion of a preferred embodiment;

Figure 3 shows a cut away side view of a portion of a preferred embodiment;

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A percutaneous lead assembly for supplying electrical signals to a medical device implanted within a body of a patient, said lead assembly comprising a flexible elongate member having a first portion adapted to remain external to the body of a patient, said first portion having a first diameter; and a second portion joined to said first portion and adapted to extend through a hole in a skin layer of the body of the patient, and wherein said second portion having a second diameter which is substantially smaller than said first diameter.

2. The percutaneous lead assembly as claimed in claim 1, wherein said first portion includes a shielding layer.

3. The percutaneous lead assembly as claimed in claim 1 or claim 2, wherein at least a segment of said second portion is covered with a textured surface.

4. The percutaneous lead assembly as claimed in claim 1, wherein said first portion and said second portion are joined by connectors.

5. The percutaneous lead assembly as claimed in claim 1, wherein said percutaneous lead assembly includes a lead restraint.

6. The percutaneous lead assembly as claimed in claim 5, wherein said lead restraint is implanted within a body of a patient and extends through a hole in the patient's skin and characterised in that an excess length of lead is releasably secured near to the hole by releasable securing means affixed to the patient's skin.

7. A percutaneous lead assembly for supplying electrical signal to a medical device implanted within a body of a patient, wherein said lead assembly has